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No. 02-

IN THE

Supreme Court of the United States

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.,
Petitioner,

v.

BIOMEDICAL SYSTEMS CORPORATION,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a manufacturer who seeks expedited marketing clearance for a medical device from the Food and Drug Administration ("FDA") – and thereby avoids extensive FDA safety and effectiveness review – violates federal law by submitting a false application to the FDA that fails to disclose the true intended use of the device and instead discloses an intended use that the manufacturer has no intention of promoting, and for which no physician will prescribe the device.

PARTIES TO THE PROCEEDING

The only parties to the proceeding are the Petitioner and Respondent listed in the caption. In the proceedings below, petitioner was identified as GE Marquette Medical Systems, Inc.

Pursuant to Rule 29.6 of the Rules of this Court, Petitioner states that it is a wholly owned subsidiary of General Electric Company. Petitioner further states that no publicly traded company owns ten percent or more of the stock of General Electric.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner GE Medical Systems Information Technologies, Inc. ("GE") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

OPINIONS BELOW

The opinion of the Eighth Circuit was entered on April 23, 2002, is reported at 287 F.3d 707, and is reproduced in the appendix hereto ("App.") at 1a-3a. The order denying GE's Petition for Rehearing and Rehearing en Banc, App. 7a, was entered on July 19, 2002, and is not reported. The final judgment of the United States District Court for the Eastern District of Missouri was entered on April 10, 2001, and is not reported. It is reproduced in the appendix at 4a-5a.

JURISDICTION

The Eighth Circuit entered its judgment in this case on April 23, 2002, App. 1a-3a, and denied the Petition for Rehearing en Banc on July 19, 2002. App. 7a. The jurisdiction of the Eighth Circuit was based on 28 U.S.C. § 1332. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The statutes at issue in this case are 21 U.S.C. §§ 360(k), 360c(f)(1), (i)(1)(A), and 360e(a)-(b)(1), and are reproduced at App. 8a-11a. The regulations at issue in this case are 21 C.F.R. §§ 801.4 and 807.87(e)-(f), and are reproduced at App. 12a-13a.

STATEMENT OF THE CASE

The Eighth Circuit's extraordinary decision in this case poses a significant threat to the integrity of the regulatory process used to grant expedited marketing authority for new medical devices. In that expedited process, the Food and Drug Administration ("FDA") does not conduct a full-blown review of the safety and effectiveness of a new device, but instead determines only whether the new device is "substantially equivalent" to certain devices already lawfully on the market. To determine substantial equivalence, the FDA is required to examine whether the new device has the same "intended use" as the device already on the market.

In the decision below, the Eighth Circuit held that it does not violate federal law for a manufacturer to misrepresent the intended use of a medical device for which the manufacturer seeks expedited marketing clearance. That ruling undermines a principal safeguard of the expedited clearance process, threatens patient health and conflicts with the Third Circuit's contrary conclusion in *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), *rev'd on other grounds*, *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2000), as well as with the FDA's authoritative interpretation of its governing regulations. Indeed, the FDA has explained that a manufacturer must disclose the actual use for which the manufacturer intends to market and distribute a medical device, and cannot rely on an intended use that is merely "a pretext calculated to clear the device for distribution for other uses." Brief of *Amicus* Food and Drug Administration at 15, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2000) (No. 98-1768) ("FDA *Amicus* Br.").

The Eighth Circuit's decision in this case raises questions of exceptional importance. It affirmatively countenances deceit of government regulators and the gaming of a regulatory system designed to ensure the safety of those who

use medical devices. At a time of heightened public and congressional concern over corporate malfeasance, the need to promote honest and candid dealings with regulators charged with protecting public health and safety could not be more compelling. Yet the decision below punishes petitioner for following the directions of FDA regulators and for refusing to submit a pretextual request for expedited marketing clearance. As a result, the decision can only encourage less scrupulous entities to file misleading submissions with the agency. And, even if the FDA succeeds in detecting misrepresentations, its ability to punish dishonest manufacturers will be undermined by the Eighth Circuit's decision, which manufacturers can cite as authority for the proposition that failure to disclose the sole intended use of a medical device is entirely permissible. This Court should grant the petition and review the lower court's plainly erroneous decision.

A. Statutory and Regulatory Background

Congress first provided the FDA with authority to regulate the marketing and distribution of medical devices in 1976. By the early 1970s, Congress recognized that many medical devices available to the public ranged from completely ineffective to extremely dangerous. In response to mounting consumer and regulatory concern, Congress amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), ch. 675, 52 Stat. 1040 (1938), and enacted the Medical Device Amendments of 1976 ("MDA" or "Act"), Pub. L. No. 94-295, 90 Stat. 539 (both statutes codified as amended at 21 U.S.C. § 301 *et seq.*).

The MDA categorizes medical devices into three separate classes based upon the risk they pose to the public. Class I devices are "those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2000); see also 21 U.S.C. § 360c(a)(1)(A). Class II devices are "those possessing a greater potential

dangerousness and thus warranting more stringent controls." *Buckman*, 531 U.S. at 344. Class III devices are those that either present "a potential unreasonable risk of illness or injury," or those which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Class III devices must undergo a time-consuming, premarket approval ("PMA") process before they may be marketed to the general public. All devices that were not in commercial distribution prior to 1976 are automatically classified as Class III devices. *Id.* § 360c(f)(1).

Given the significant public health and safety concerns associated with the introduction of new medical devices, the FDA's regulatory scrutiny is intensive. Thus, to obtain premarket approval, manufacturers of new devices are required to submit information to the FDA that provides "reasonable assurance" that the device is both safe and effective. *Id.* § 360e(d)(2). Although this PMA procedure is costly and time-consuming, requiring the submission of voluminous information that details the safety and effectiveness of the device, it is vital to ensuring that the public's health is protected. This is why the FDA spends approximately 1,200 hours reviewing and processing each PMA submission. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 477 (1996) (citing *Hearings before the Subcomm. on Health and the Environment of the House Comm. on Energy & Commerce*, 100th Cong. 384 (1987)).

B. The 510(k) Exception

The MDA provided several important exceptions to the PMA process. First, it allowed "pre-amendment" Class III devices – *i.e.*, Class III devices that were on the market prior to passage of the MDA – to remain on the market until the FDA completes a rulemaking requiring the submission of a PMA for each such device. 21 U.S.C. § 360e(b)(1)(A). Second, to avoid giving monopolies to such grand-fathered

devices, *Buckman*, 531 U.S. at 345, the MDA allows manufacturers to distribute new devices that are shown to be "substantially equivalent" to a pre-amendment Class III device. 21 U.S.C. § 360e(b)(1)(B).[1] Third, the MDA allows manufacturers to distribute new devices that are shown to be "substantially equivalent" to any devices, whether pre- or post-amendment, that are classified as Class I or Class II devices. *Id.* § 360c(f)(1).

Manufacturers seeking marketing authorization for new devices under the last two exceptions must use what is referred to as the 510(k) notification process.[2] This fast-track process involves a limited form of agency review that focuses only on the question of whether the new device is "substantially equivalent" to a predicate device. Under the statute, a device is "substantially equivalent" if it "has the *same intended use* as the predicate device" and if the FDA finds either that it has the "same technological characteristics as the predicate device," or is at least "as safe and effective as a legally marketed device." *Id.* § 360c(i)(1) (emphasis added). To establish "substantial equivalence," a manufacturer must submit, among other things, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, *its intended use*, and the directions for its use," and "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement." 21 C.F.R. § 807.87(e), (f) (emphasis added). The statute affords the FDA 90 days to determine whether the device is "substantially equivalent." 21 U.S.C. § 360(k).

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[1] Once the FDA completes the rulemaking requiring a PMA for the pre-amendment Class III device, any "substantially equivalent" post-amendment devices must likewise submit a PMA. *See* 21 U.S.C. § 360e(b)(1)(B).

[2] Section 510(k) of the MDA is codified at 21 U.S.C. § 360(k). Pub. L. No. 94-295, sec. 4(k), § 510(k), 90 Stat. at 580.

While a standard PMA review takes over 1,200 hours for the agency to complete, a 510(k) notification review is completed in an average of about 20 hours. *Medtronic*, 518 U.S. at 478-79. In sharp contrast to a PMA, the 510(k) notification "'requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'" *Id.* at 479 (quoting Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)). Not surprisingly, device manufacturers find the 510(k) process preferable to the more onerous PMA process.[3]

Both processes, however, are similar in that thorough disclosures and accurate information are critical to the FDA's ability to protect health and safety. The manufacturer's representations concerning the "intended use" of a device, therefore, play a crucial role in ensuring that the expedited 510(k) process does not allow unsafe devices to reach the public. In a 510(k) proceeding, the FDA does not determine that either the new device or the predicate device is safe. See *Medtronic*,, 518 U.S. at 479. Instead, Congress reasonably concluded that if a device is already in commercial use, permitting a substantially equivalent device to reach the market was unlikely to harm the public. But, because a medical device that is safe for one use may be unsafe for another, Congress directed the FDA, when making a "substantial equivalence" determination, to examine whether the new device "has the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1).

Under FDA regulations, "intended use" must be determined based on the "objective intent of the persons legally responsible for the labeling of [the] device[]." 21 C.F.R.

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[3] As of 1990, over 80% of new Class III devices were being introduced to the market through the 510(k) process. H.R. Rep. No. 101-808, at 14 (1990); *Medtronic*, 518 U.S. at 479.

§ 801.4. A device's labeling is thus relevant to, but not dispositive in, determining the use the manufacturer intends for the device. Other relevant evidence includes "advertising matter," a manufacturer's "oral or written statements," and the manufacturer's "knowledge" that the device is "offered and used for a purpose for which it is neither labeled nor advertised," or that it "is to be used" for purposes other than those for which the manufacturer has offered it. *Id.* Accordingly, when the FDA "seeks from an applicant a statement of a device's intended use, it is not simply asking for the use that will appear on the labeling." FDA *Amicus* Br. at 14-15.

The FDA recognizes that physicians often use medical devices for purposes that are not identified in the devices' labeling, and it does not require manufacturers seeking 510(k) clearance to disclose every possible "off-label" use to which the device might be put. The FDA has stated, however, that:

> when, at the time of the application, a manufacturer plans to promote and distribute a device *exclusively* for one use, it must disclose to FDA that intended use. A statement to FDA that the device has a different intended use would be false and misleading. The intended use stated in the premarket notification must be a bona fide use; *it cannot be a pretext calculated to clear the device for distribution for other uses.*

Id. at 15 (emphases added).[4]

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[4] Accurate disclosure of intended use took on even greater importance in light of the FDA Modernization Act of 1997 ("FDAMA"). That Act provides that, for a period of five years, when the FDA makes substantial equivalence determinations, determinations of intended use "shall be based upon the proposed labeling." 21 U.S.C. § 360c(i)(1)(E)(iv). The FDAMA thus makes it imperative that a manufacturer disclose the actual intended uses of its device: if the intended use on the label is merely a pretext, a determination that this pretextual use is the same that of the predicate device fails to provide any assurance of safety and effectiveness – precisely what substantial equivalence determinations are intended to

C. FDA Classification of Home Uterine Activity Monitors

This case involves a medical device known as a home uterine activity monitor ("HUAM"). Uterine activity monitors were in commercial distribution prior to enactment of the MDA and, in 1980, the FDA listed these devices as Class II devices. Obstetrical and Gynecological Devices; Classification of External Uterine Contraction Monitors and Accessories, 45 Fed. Reg. 12,696, 12,696 (Feb. 26, 1980) (to be codified at 21 C.F.R. § 884.2720). Accordingly, substantially equivalent new products were qualified to apply for clearance under § 510(k).

During the early 1980s, the FDA granted several 510(k) clearances for uterine activity monitors that were intended for use by women at full-term. Physicians, however, soon began to prescribe the devices for a new use: early detection of pre-term labor in high-risk patients at home. Obstetrics and Gynecology Devices; Reclassification of Home Uterine Activity Monitor, 64 Fed. Reg. 41,435, 41,436 (July 30, 1999) (notice of panel recommendation). Physicians found the HUAM to be helpful in detecting pre-term labor, especially because the woman did not need to be present in a clinical setting to have her contractions monitored.

This new use of HUAMs, however, posed a new set of risks. The most troublesome was an increased risk of a false positive, indicating pre-term labor when none was present. A false diagnosis of this type often resulted in unnecessary hospitalization, potentially risky drug treatment, and deleterious patient stress. *Id.* at 41,437.

As these problems were coming to light during the 1980s and early 1990s, several manufacturers submitted 510(k)

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provide. *See* FDA *Amicus* Br. at 16 n.2 (FDAMA "underscores why a manufacturer seeking Section 510(k) clearance for a device must disclose all intended uses of the device, and not merely those set forth in [the] proposed labeling").

notifications for HUAMs stating that the device was intended for full-term monitoring. After granting several of these applications, the FDA became increasingly concerned that the monitors were in fact being marketed for the riskier use of pre-term monitoring. Appendix of Defendant-Appellant at 341-43, *Biomedical Sys. Corp.* v. *GE Marquette Med. Sys., Inc.*, 287 F.3d 707 (8th Cir. 2002) (No. 01-3076) ("Appellant App."). Ultimately, it determined that use of HUAMs for the early detection of pre-term labor constituted a new intended use, and that, for this new use, "the HUAM was not substantially equivalent to any . . . device . . . that had been classified into class I or class II for the early detection of [pre-term labor]." 64 Fed. Reg. at 41,436. The FDA changed the classification of the HUAM from a Class II device to a Class III device, and advised manufacturers that the device "*could not be placed in commercial distribution for early detection of [pre-term labor]* in high risk patients *unless it was reclassified . . . or subject to an approved PMA*." *Id.* (emphasis added).

By 1992, the FDA's change in regulatory policy was complete. The agency granted no 510(k) clearances for a HUAM claimed to be intended for term use after 1992. Appellant App. 344. HUAM manufacturers seeking to market such devices had only two options: (1) submit to the thorough PMA process, or (2) petition the FDA for reclassification of the device. Indeed, in 1993, an FDA advisory panel concluded that the HUAM was "a good candidate for reclassification" and invited manufacturers "to petition FDA for a change in classification of the devices." 64 Fed. Reg. at 41,437.

D. The Underlying Dispute

Respondent Biomedical Services ("Biomedical") provides HUAMs to women with high-risk pregnancies who are at risk of pre-term labor. It offers daily or weekly "Pre-term Labor Management" services, and its promotional materials focus on the benefits of HUAMs for women who are at risk of pre-

term labor. Women who are at term, and by definition no longer at risk of pre-term labor, have no need for Biomedical's products or services.

In the early 1990s, Biomedical developed the technology for a new HUAM. In April 1996, it began negotiating with GE's predecessor in interest, Corometrics, a company which had the capacity to manufacture the HUAM and a sizeable sales force for distributing and marketing it. During this initial meeting, Corometrics informed Biomedical's owner and founder, Ray Barrett, that "you cannot do a 510(k)" for the new monitor. Appellant App. 35. One month later, Biomedical's own regulatory specialist likewise confirmed that, before obtaining FDA clearance for the HUAM, the FDA would need to "reclassify the device from its current class III to a class I or II" to make "it easier to obtain market clearance for our device and desire[d] use." Appellant App. 452. "We should pursue this [reclassification] direction no matter what else we do. . . . [O]nce a reclassification occurs, a 510(k) will need to be filed." *Id.*

On January 28, 1997, the parties executed a Technology Transfer Agreement ("Agreement") in which Corometrics agreed to "obtain clearance for a 510(k) application," *id.* at 455 (¶ 1), and to ensure that "the Monitor has qualified for a 510(k) application." *Id.* at 456 (¶ 3). Corometrics concluded that, in order to comply with this obligation, it simultaneously had to petition the FDA for reclassification of a pre-term monitor as a Class II device, and file a 510(k) that would be granted immediately upon the HUAM's re-classification. In fact, FDA officials recommended this precise course of action. *Id.* at 335.

After Corometrics filed the reclassification petition, however, groups such as the National Women's Health Network and the American College of Obstetricians and Gynecologists strenuously opposed it on health and safety grounds. This intense opposition substantially delayed the reclassification process. *Id.* at 673. Nevertheless, for two

years after signing the Agreement, Biomedical stood by its support of Corometrics' decision. After GE acquired Corometrics, however, Biomedical filed suit, alleging that, by failing to file a 510(k) notification for *term* use, GE's predecessor had breached the Agreement.

E. This Litigation

In the trial court, Biomedical claimed that GE was contractually obligated to file a 510(k) submission claiming that the device was intended for *term* use, even though the parties never intended to market the device for that use and instead intended to market it solely for pre-term monitoring. GE argued that the contract could not have the meaning Biomedical ascribed to it because, so construed, the contract would have required GE to file an application misrepresenting the HUAM's intended use, in violation of FDA regulations and federal criminal law. The district court ruled, however, that the meaning of the contract was ambiguous, and that its meaning was a question of fact for the jury. *Biomedical Sys. Corp.* v. *GE Marquette Med. Sys., Inc.*, No. 4:99-CV-1590-CAS, slip op. at 6 (E.D. Mo. Mar. 1, 2001) (order denying motions to dismiss and for summary judgment).

The evidence at trial confirmed that the sole intended use of the monitor was for pre-term pregnant women. Biomedical promotes its monitoring services as appropriate for home use by pre-term pregnant women. The sole use identified in Biomedical's complaint was pre-term monitoring, and the damage formula Biomedical presented at trial relied entirely on alleged "lost profits" from pre-term use of the monitor. Biomedical's own medical expert testified that he had never used a HUAM for purposes of detecting contractions in a full-term patient, and GE's expert testified that he could not imagine why anyone would now prescribe the device for full

term use. Biomedical offered no evidence that the device was in fact ever prescribed for term use.[5]

The district court refused to consider the fact that Biomedical's interpretation would have resulted in an agreement that was illegal, and thus unenforceable, under the FDA's regulation. Instead, the judge allowed Biomedical to argue that the contract required GE to file a pretextual 510(k) for term use, and he barred GE from offering rebuttal evidence regarding the FDCA violations that would result from such a reading.[6] As a result, the jury returned a verdict in favor of Biomedical for breach of contract and assessed $75 million in damages against GE.

F. Decision of the Eighth Circuit

On appeal, GE again argued that, as Biomedical construed it, the contract was unenforceable because it would require the filing of a false and misleading application. Biomedical's response made unmistakably clear that it sought to hold GE liable for failing to file a purely pretextual 510(k) submission. Biomedical claimed that GE should have "fil[ed] a 510(k) for term use," and then "*covered its flanks*" with labels stating that the device was not approved for pre-term monitoring. Br. of Appellee at 41, 43 (emphasis added). Biomedical argued that, because the FDAMA restricts the FDA's determination of "intended use" to the use disclosed in the proposed label, labels stating that the device was approved only for term use would have completely shielded GE from any charge of

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[5] A Biomedical nurse stated that 10% of *pre-term* patients continue to wear the device after they reach full term. Trial Tr. XII-B-54-55. In such circumstances, of course, the device is neither prescribed nor intended for full term use.

[6] In response to GE's repeated attempts to introduce evidence that Biomedical's proposed interpretation of the contract would require GE to commit a fraud on the FDA, the trial judge said: "Legal, illegal, forget it. Right, wrong, forget it.... Whether it was right, wrong, good, bad, screw all that." Appellant App. 111-12.

falsity or illegality, *id.* at 31 – even though the HUAM was indisputably *not* intended for term use and no physician would ever prescribe it for such use. According to Biomedical, FDA regulations that require applicants to base "intended use" on knowledge that a device will be offered and used for purposes that do not appear on the label are simply irrelevant in light of the FDAMA. *Id.* The FDA's contrary "analysis of 'intended use' in the *Buckman amicus* brief," Biomedical claimed, "is mistaken." *Id.* at 41.

The Eighth Circuit accepted these arguments in a brief, per curiam opinion. According to the lower court, "the contract unambiguously required GE to apply for 510(k) clearance and *did not require GE to violate federal law*." App. 2a-3a (emphasis added). The Eighth Circuit's key holding that the contract, as construed by Biomedical, was not illegal allowed the court to affirm the $75 million damages verdict that the jury assessed against GE for failing to file a pretextual 510(k) notification. The court denied the petition for rehearing and rehearing en banc without opinion on July 19, 2002.

REASONS FOR GRANTING THE PETITION

The decision below conflicts with the Third Circuit's holding in *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), and with the FDA's authoritative interpretation of the regulations that govern the 510(k) application process. Indeed, both the Third Circuit and the FDA, in its Buckman *Amicus* Brief, explicitly condemned the very actions that the lower court approved in this case. Permitting manufacturers to evade meaningful regulation by misrepresenting the intended use of a medical device will greatly hamper the FDA's ability to do its job. Indeed, a holding that does such violence to the integrity of a regulatory scheme intended to protect public health and safety is of exceptional importance.

The significance of the erroneous ruling below is not diminished by the Eighth Circuit's cursory effort to explain the basis of its judgment. The issue of whether a manufacturer can submit a 510(k) notification that fails to disclose the actual intended use of a medical device was squarely presented and fully aired below. Petitioner cited the FDA's regulations, and the agency's interpretation of those regulations, and argued at length that the regulations rendered respondent's interpretation of the contract illegal. Respondent claimed that the regulations were irrelevant under the FDAMA, and dismissed the FDA's contrary view as "mistaken." The Eighth Circuit expressly addressed the issue, holding that it would "not . . . violate federal law" for GE to file a 510(k) notification that the FDA, and the Third Circuit, would deem false and misleading. The Eighth Circuit's holding is binding precedent, and creates a conflict both among the circuits and between the Eighth Circuit and the federal agency charged with administration of the federal statutes at issue.

The import of the Eighth Circuit's holding, moreover, will not be lost on medical device manufacturers. Manufacturers are sophisticated entities, subject to an elaborate and complex regulatory regime, with obviously strong incentives to use the expedited and far less expensive 510(k) process to bring new products to market. A $75 million verdict against a fellow manufacturer will not escape notice within this community, particularly a verdict predicated on the theory that FDAMA overrides the FDA's intended use regulations, and permits a manufacturer to label a device for a use that is not actually intended.

The Eighth Circuit's erroneous decision thus creates a serious risk that other manufacturers will embrace respondent's view of the regulatory scheme, and will submit 510(k) notifications that, under the FDA's contrary – and indisputably correct – view of the law, are false and misleading. The FDA, in turn, will be forced to devote

limited resources to detecting such 510(k) submissions. And even if it succeeds in identifying such submissions, the manufacturers can cite the Eighth Circuit's ruling to show that their conduct is permissible.

I. THE RULING BELOW CONFLICTS WITH A DECISION OF THE THIRD CIRCUIT.

In *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), the Third Circuit held that an applicant for 510(k) clearance cannot "represent[] that it intend[s] to market its device for one use when, in fact, it intend[s] at the time of the application to market that device solely for another, more hazardous use." *Id.* at 828. That ruling remains good law in the Third Circuit. The Eighth Circuit's ruling in this case simply cannot be reconciled with the Third Circuit's ruling.

In *Orthopedic Bone Screw*, a manufacturer twice sought FDA clearance for a bone screw for use in spinal surgery. After the FDA denied both applications on the ground that the device was not substantially equivalent to a pre-existing device, the manufacturer filed a third notification stating that the device was intended for use in arm and leg surgery. Based upon this "revised" statement of intended use, the FDA granted 510(k) approval. The manufacturer thereafter marketed the bone screw to physicians for spinal surgery. The bone screws proved to be unsafe for use in spinal surgery, and the many individuals injured by that use sued the manufacturer under state law, alleging fraud-on-the-FDA.

The manufacturer argued that the claims against it had to be dismissed because, as a matter of federal law, a statement of intended use by a 510(k) applicant is not a representation of actual marketing intentions upon which the FDA can rely in granting market clearance, but rather is a description of the authority the manufacturer seeks. *Id.* at 826-27. Like respondent, the manufacturer argued that "the sole interest of the FDA in the applicant's intended use is to enable [the

FDA] to limit the authority granted to that which is sought and considered by the agency." *Id.* at 827. Any concerns about "off-label" use of a device, it argued, can be addressed through labeling restrictions. *Id.*

The Third Circuit emphatically disagreed, stating that:

> [t]o the extent [the manufacturer's] argument is an assertion of law, we find no basis for it in the statute, in the regulations, or in any of the authorities cited . . . . Because the degree of risk presented by any device is a function of the use to which it is put, the intended use is thus a central focus in the FDA review. *Indeed, there is nothing more material to its determination of whether to grant access to the market.*

Id. at 828 (emphasis added).

The court recognized "that a manufacturer unable lawfully to secure a § 510(k) clearance for one purpose may legally be entitled to a § 510(k) clearance for the same device when put to a different purpose." *Id.* But, in words fully applicable to this case, the Third Circuit held that a manufacturer cannot secure 510(k) clearance "by representing that it intend[s] to market its device for one use when, in fact, it intend[s] at the time of the application to market that device solely for another, more hazardous use." *Id.* Such a representation, the Third Circuit held, was "fundamentally at odds with the [FDA's] gatekeeping assignment," and struck at the heart of the regulatory regime, because "[a] device that presents no risk of injury when employed for one purpose may present great risk of injury when employed for another." *Id.*

It is thus clear that, under the law of the Third Circuit, GE could *not* have "fil[ed] a 510(k) for term use," and then "covered its flanks" with labels stating that the device was not approved for pre-term monitoring. Br. of Appellee at 41, 43. The Third Circuit would rule – correctly – that a contract requiring such conduct is illegal and unenforceable. The

Eighth Circuit, however, squarely held that such a contract "did not require GE to violate federal law." App. 2a-3a.

Although this Court reversed the Third Circuit's conclusion that state law fraud-on-the-agency claims are not preempted, *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2000), the Court did not disagree with, or cast any doubt upon, the Third Circuit's holding that a manufacturer cannot represent that it intends to market a device for one use when it intends at the time of the application to market that device solely for another use. Rather, this Court reasoned that it was the FDA's "responsibility to police fraud," and that allowing juries to punish fraud on the agency under state law would inevitably result in conflicts with the FDA's exercise of that responsibility. *Id.* at 350. Thus, the Third Circuit's ruling that a manufacturer must disclose its actual marketing intentions for a device, and that a failure to do so was "fundamentally at odds" with the 510(k) regime, remains good law, and conflicts with the central basis for the holding of the Eighth Circuit here. Indeed, the FDA, which urged preemption of state tort claims, fully *agreed* with the Third Circuit's ruling in this regard. See *infra*, § II.

II. THE EIGHTH CIRCUIT'S DECISION CONFLICTS WITH THE FDA'S AUTHORITATIVE INTERPRETATION OF THE REGULATIONS GOVERNING THE 510(K) PROCESS.

In the *amicus* brief filed in *Buckman*, the FDA expressly rejected the very theories that respondent advanced – and the Eighth Circuit accepted – in this case. Because an agency's interpretation of its own regulations is entitled to the highest degree of judicial deference, *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997) (applying principle to views set forth in an *amicus* brief), the Eighth Circuit's failure to follow the views of the agency charged with administering the federal statutes at issue in this case provides an additional compelling reason for review by this Court.

The petitioner in *Buckman*, like respondent here, argued that, "under federal law, 'intended use' refers to the use set forth in the labeling," not the "manufacturer's subjectively desired off-label uses." FDA *Amicus* Br. at 14. The FDA explained that this claim "misreads . . . the applicable federal standards." *Id.* "[W]hen FDA seeks from an applicant a statement of a device's intended use, it is *not simply asking for the use that will appear on the labeling*." *Id.* at 14-15 (emphasis added). Rather, federal law requires a manufacturer to disclose "the intended use that will be revealed by all of the manufacturer's 'expressions' and 'the circumstances surrounding' the device's 'distribution.'" *Id.* at 15 (quoting 21 C.F.R. § 804.1). These "surrounding circumstances" and "expressions" include not only the proposed labeling, but also (1) "'advertising matter,'" (2) a manufacturer's "'oral or written statements,'" (3) the manufacturer's "'knowledge'" that a product is "'offered and used for a purpose for which it is neither labeled nor advertised,'" and (4) the manufacturer's knowledge of facts that would give him "'notice'" that a product "'is to be used'" for purposes other than those for which the manufacturer offered it. *Id.* at 14; see also *United States* v. *Bowen*, 172 F.3d 682 (9th Cir. 1999) (intended use "'may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.'").

Embracing the views of the Third Circuit, the FDA emphasized that when:

> a manufacturer plans to promote and distribute a device exclusively for one use, it *must* disclose to FDA that intended use. A statement to FDA that the device has a different intended use would be *false and misleading*. The intended use stated in the [510(k)] must be a bona fide use; it cannot be a pretext calculated to clear the device for distribution for other uses.

FDA *Amicus* Br. at 15 (emphases added).

The FDA also flatly rejected the theory that the FDAMA rendered the agency's "intended use" regulations irrelevant. This Act, the FDA explained, "does not relieve manufacturers of their obligation . . . to truthfully inform FDA of a device's 'intended use' as that term is defined in FDA's 'intended use' regulation, 21 C.F.R. 801.4." *Id.* at 15 n.2. The agency noted that other provisions of the FDAMA authorized the FDA to require statements on labels if it determines that "there is a reasonable likelihood that the device will be used for an intended use *not identified in the proposed labeling*." 21 U.S.C. § 360c(i)(1)(E)(i)(I) (emphasis added). This authority, the FDA explained, "underscores why a manufacturer . . . must disclose all intended uses of the device, not merely those set forth in whatever proposed labeling the manufacturer chooses to submit in the Section 510(k) clearance process." FDA *Amicus* Br. at 16 n.2.

The FDA's authoritative interprepretation of the governing regulations makes clear that GE could not have filed a 510(k) notification for term use and then "covered its flanks" with labeling disclaimers when the parties had no intention of marketing the device for term monitoring and knew that no physician would ever prescribe it for such use. Contrary to respondent's view, the FDA's interpretation is not "mistaken," Br. of Appellee at 41, but entitled to great deference. *Auer*, 519 U.S. at 461. Indeed, its position that applicants must file truthful applications is unassailable, as such information is indispensable to the proper functioning of the regulatory scheme governing the marketing of medical devices. Because the Eighth Circuit upheld a contract interpretation that required conduct violative of the FDA's 510(k) regulations, this Court should grant the petition and reverse the lower court's clear error.

III. THE EIGHTH CIRCUIT OPINION UNDERMINES THE INTEGRITY OF A REGULATORY REGIME DESIGNED TO PROTECT THE HEALTH AND SAFETY OF AMERICANS.

The Eighth Circuit's decision in this case not only fails to pay appropriate deference to the FDA's interpretation of its own regulations (and to the views of a sister circuit), it affirmatively countenances deceit of government regulators and the gaming of a regulatory system primarily designed to ensure "the safety of those who use medical devices." *Medtronic*, 518 U.S. at 491. The need to promote honest and forthright behavior by regulated entities – particulary entities whose products directly affect the public health and safety – could hardly be greater. Yet, at a time of extraordinary public and congressional concern over corporate malfeasance, the Eighth Circuit has ruled that submission of a pretextual 510(k) does not violate the Medical Device Act. Because the decision severely frustrates the primary objective of that law, it deserves special scrutiny by this Court.

As the facts of *Buckman* demonstrate, the 510(k) process, which combines modest agency review with significant competitive advantages, creates incentives that can lead some manufacturers to game the system, with disastrous results for the public's health and safety. In *Buckman* itself, the manufacturer relied on the advice of a regulatory consultant, who hatched the strategy of limiting the labels for the bone screws to one form of surgery, even though the manufacturer intended and expected that the product would only be used for a different type of surgery. See *Orthopedic Bone Screws*, 159 F.3d at 820. Sophisticated consultants who help manufacturers navigate this complex regulatory regime will make use of the Eighth Circuit's decision to uphold a $75 million jury verdict that was based on the theory that it is permissible to file a pretextual 510(k) application. Coupled with this Court's preemption of common law fraud-on-the-agency claims, the Eighth Circuit's decision can only serve to induce

consultants and manufacturers to adopt Biomedical's "cover your flanks with labeling" approach to 510(k) submissions. This will increase the risk that new medical products that are unsafe for their actual intended uses will reach the public.

To be sure, the FDA has tools at is disposal to detect, deter and punish false statements made during the 510(k) process. The FDA is empowered to investigate fraud, 21 U.S.C. § 372; 21 C.F.R. § 5.35, and may respond by seeking injunctive relief or civil penalties, seizing the device, or even pursuing criminal prosecutions. See 21 U.S.C. §§ 333(a), (f)(1)(A), 334(a)(2)(D); see also, *e.g.*, *United States* v. *Barile*, 286 F.3d 749 (4th Cir. 2002) (involving prosecution for materially false statements made to the FDA on 510(k) submissions). But the agency cannot be expected to detect all misleading 510(k) submissions, and efforts to do so will divert agency resources from other important activities aimed at protecting and promoting the public health and safety.

Moreover, even if the agency succeeds in identifying all of the pretextual, "cover your flanks" 510(k) submissions that the Eighth Circuit's decision will yield, that decision will pose a significant barrier to successful punishment of such filings. A manufacturer charged with making a criminally false and misleading 510(k) submission will undoubtedly seek refuge in the Eighth Circuit's holding that it does "not . . . violate federal law" for a 510(k) applicant to omit the actual intended use of a new medical device. By casting doubt on the illegality of such conduct, the Eighth Circuit's decision will undermine the deterrence value of potential criminal sanctions.

In short, the decision below creates perverse incentives for manufacturers to circumvent FDA regulations, thereby undermining a regulatory regime designed to protect the public health and safety. As manufacturers take their cue from the Eighth Circuit, the FDA runs the risk of making equivalency determinations based upon incomplete, inaccurate, misleading and even fraudulent data. A holding

that so blatantly frustrates a regulatory scheme designed to protect the public health warrants this Court's careful review.

CONCLUSION

For the reasons stated above, the Court should grant the petition for writ of certiorari.

Respectfully submitted,

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October 17, 2002

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
EIGHTH CIRCUIT

No. 01-3076

BIOMEDICAL SYSTEMS CORPORATION,
Appellee,

v.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Appellant.

Submitted: April 16, 2002.
Filed: April 23, 2002.

Before HANSEN, Chief Judge, McMILLIAN and FAGG, Circuit Judges.

PER CURIAM.

GE Marquette Medical Systems, Inc. (GE) appeals from an adverse jury verdict in this diversity action. Having carefully reviewed the briefs, record, and arguments of counsel, we are satisfied the district court * correctly applied state law, and the challenged rulings do not require reversal. Because the parties' submissions show they are thoroughly familiar with the issues before this court, we conclude that an extended opinion in this diversity case would serve no useful purpose.

Before GE acquired Corometrics, Inc. (Corometrics), Corometrics contracted to produce a new home uterine activity monitor (HUAM) based on technology developed by

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* The Honorable Charles A. Shaw, United States District Judge for the Eastern District of Missouri.

Biomedical Systems Corporation (Biomedical). (Because Corometrics is now part of GE, we refer to Corometrics as GE.) HUAMs are medical devices regulated by the Food and Drug Administration (FDA). The GE-Biomedical contract required GE to obtain "510(k)" premarket notification clearance from the FDA. *See* Food, Drug, and Cosmetic Act, ch. 675 § 510(k), 76 Stat. 794 (1962) (codified as amended at 21 U.S.C. § 360(k) (1994)). To receive 510(k) clearance, a manufacturer must give the FDA 90 days' notice that the manufacturer intends to market a medical device (1) which is substantially equivalent to a device already approved by the FDA, and (2) which has the same intended use as the approved device. *Id.* If the FDA agrees, it issues a clearance letter which authorizes the manufacturer to market the device as specified by the FDA.

Rather than seeking 510(k) approval, which would be granted or denied within 90 days, GE asked the FDA to reclassify GE's new HUAM from one class of regulated devices to another class of regulated devices. The reclassification process took three and a half years. Two and a half years after signing the contract, Biomedical sued GE in federal district court alleging fraudulent misrepresentation and breach of contract, and claiming $135 million in damages. The jury found for Biomedical on its breach of contract claim and awarded $75 million in damages. On appeal, GE challenges the district court's rulings barring its illegality and waiver defenses.

First, GE argues it was entitled to judgment as a matter of law because the contract, which GE drafted, required GE illegally to seek 510(k) approval for the new HUAM. Having reviewed this issue de novo, *Fogelbach v. Wal-Mart Stores, Inc.*, 270 F.3d 696, 700 (8th Cir.2001), we conclude the district court properly denied GE judgment as a matter of law on its illegality defense. In our view, the contract unambiguously required GE to apply for 510(k) clearance and did

not require GE to violate federal law. Indeed, after considering the contractual language in light of extrinsic evidence about the parties' intent when entering into the contract, the jury reached the same conclusion.

Second, GE contends the district court improperly excluded evidence that Biomedical waived GE's breach of the contract provisions requiring GE to seek 510(k) approval. The GE-authored contract, however, expressly forbids waiver of this sort. Because the contract is governed by Connecticut law under which the waiver provision is valid, *see Christensen v. Cutaia,* 211 Conn. 613, 560 A.2d 456, 459 (Conn.1989), we conclude the district court correctly barred GE's waiver defense.

Having satisfied ourselves that the district court correctly rejected GE's illegality and waiver defenses, we also reject GE's remaining arguments. Because the contract did not require illegal conduct on GE's part, we do not disturb the jury damage award. Further, the district court did not abuse its discretion when it excluded evidence that supported and refused to give requested instructions that explained the illegality and waiver defenses.

In sum, whether discussed or not, we have considered all of GE's arguments. Finding no error that would require reversal, we affirm the judgment of the district court.

APPENDIX B

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

[Filed Apr 10, 2001]

No. 4:99 CV-1590 CAS

BIOMEDICAL SYSTEMS CORPORATION,
Plaintiff,

v.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Defendant.

JUDGMENT

This matter came on for trial before a jury, the undersigned United States District Judge presiding. The issues were duly tried and the jury rendered its verdict on April 9, 2001, in favor of plaintiff Biomedical Systems Corporation and against defendant GE Marquette Medical Systems, Inc. on Count I, and in favor of defendant GE Marquette Medical Systems, Inc. on Count II.

Accordingly,

IT IS HEREBY ORDERED, ADJUDGED and DECREED that judgment is entered in favor of plaintiff Biomedical Systems Corporation and against defendant GE Marquette Medical Systems, Inc. on plaintiff's claims in Count I for breach of contract.

IT IS FURTHER ORDERED, ADJUDGED and DECREED that plaintiff Biomedical Systems Corporation is awarded actual damages on Count I in the amount of Seventy-Five Million Dollars ($75,000,000.00), together with post-judgment interest at the rate of 4.00 percent per annum, as provided by law.

IT IS FURTHER ORDERED ADJUDGED, and DECREED that judgment is entered against plaintiff and in favor of defendant GE Marquette Medical Systems, Inc. on Count II for fraudulent misrepresentation.

IT IS FURTHER ORDERED that costs are assessed against defendant GE Marquette Medical Systems, Inc.

/s/ Charles A. Shaw
CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 10th day of April, 2001.

APPENDIX C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

[Filed Jul 16, 2001]

No. 4:99-CV-1590 CAS

BIOMEDICAL SYSTEMS CORPORATION,
Plaintiff,

v.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Defendant.

ORDER

This matter is before the Court on the Motion of Defendant for Judgment in Accordance with Motion for Judgment as a Matter of Law, or in the Alternative, Motion for a New Trial, filed pursuant to Fed. R. Civ. P. 50(b) and 59.

The Court, after careful consideration, concludes that defendant's motion for judgment in accordance with its motion for judgment as a matter of law should be denied, and that defendant's alternative motion for new trial should be denied. Accordingly,

IT IS HEREBY ORDERED that defendant's motion for judgment in accordance with its motion for judgment as a matter of law is DENIED. [Doc. 203]

IT IS FURTHER ORDERED that defendant's alternative motion for new trial is DENIED. [Doc. 203]

/s/ Charles A. Shaw
CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 16th day of July, 2001.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 01-3076

BIOMEDICAL SYSTEMS CORPORATION,
Appellee,

vs.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Appellant.

Order Denying Petition for Rehearing and
for Rehearing En Banc

The appellant's motion to file a reply memorandum in support of its petition for rehearing en banc was granted, and the voting date on the petition was extended to permit all judges to consider the reply.

The petition for rehearing en banc is denied. The petition for rehearing by the panel is also denied.

Judge Morris S. Arnold and Judge Melloy took no part in the decision in this matter.

(5128-010199)

July 19, 2002

Order Entered at the Direction of the Court:

Clerk, U.S. Court of Appeals, Eight Circuit

APPENDIX E

21 U.S.C. § 360. Registration of producers of drugs or devices

* * * *

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 360m(a) of this title (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

* * * *

(June 25, 1938, c. 675, § 510, as added Oct. 10, 1962, Pub.L. 87-781, Title III, §302, 76 Stat. 794, and amended July 15, 1965, Pub.L. 89-74, § 4, 79 Stat. 231; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(e), 84 Stat. 1282; Aug. 16, 1972, Pub. L. 92-387, §§ 3, 4(a) to (c), 86 Stat. 560 to 562; May 28, 1976, Pub.L. 94-295, § 4(a), 90 Stat. 579; Nov. 21, 1997, Pub.L. 105-115, Title I, § 125(a)(2)(C), Title II, §§ 206(a),

209(a), 213(b), Title IV, § 417, 111 Stat. 2325, 2338, 2341, 2347, 2379.)

21 U.S.C. § 360c. Classification of devices intended for human use

* * * *

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

* * * *

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(*l*)

of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

* * * *

(June 25, 1938, c. 675, § 513, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 540, and amended Nov. 28, 1990, Pub.L. 101-629, §§ 4(a), 5(a), (b), (c)(1), (c)(3), 12(a), 18(a), 104 Stat. 4515, 4517, 4518, 4523, 4528; June 16, 1992, Pub.L. 102-300, § 6(e), 106 Stat. 240; Aug. 13, 1993, Pub.L. 103-80, § 3(s), 107 Stat. 778; Nov. 21, 1997, Pub.L. 105-115, Title II, §§ 205(a), (b), 206(b), (c), 207, 208, 217, 111 Stat. 2336, 2337, 2339, 2340, 2350.)

21 U.S.C. § 360e. Premarket approval

(a) General requirement

A class III device—

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

(b) Regulation to require premarket approval

(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

* * * *

(June 25, 1938, c. 675, § 515, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 552, and amended Nov. 28, 1990, Pub.L. 101-629, §§ 4(b)(1), 9(a), 18(c), 104 Stat. 4515, 4521, 4528; Aug. 13, 1993, Pub.L. 103-80, § 3(t), 107 Stat. 778; Nov. 21, 1997, Pub.L. 105-115, Title II, §§ 201(b), 202, 205(c), 209(b), 216(b), 111 Stat. 2334, 2338, 2341, 2349.)

APPENDIX F

21 C.F.R. § 801.4. Meaning of "intended uses."

The words "intended uses" or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

21 C.F.R. § 807.87. Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

* * * *

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for

its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

* * * *

[42 FR 42526, Aug. 23, 1977, as amended at 57 FR 18066, Apr. 28, 1992, 59 FR 64295, Dec. 14, 1994; 63 FR 5253, Feb. 2, 1998]